

SEP 23 2004

K041909

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

page 1 of 2

Common/Usual Name: Intravascular Diagnostic Catheter

Product Trade Name: Dual Lumen Pigtail Catheter

Classification Name: Unclassified
Product Code, DQO

Manufacturer: Vascular Solutions, Inc.
6464 Sycamore Court
Minneapolis, Minnesota 55369

Establishment Registration: 2134812

Contact: Sara L. Coon
Senior Regulatory Affairs Associate
(763) 656-4300 phone
(763) 656-4200 fax

Performance Standards: No performance standards have been developed under section 514 for this device.

Device Description:

The Vascular Solutions Langston™ Dual Lumen Pigtail catheter is intended for use as a pressure measurement catheter and for delivery of contrast media during angiographic studies. The DLP catheter consists of the Merit Medical Softouch Diagnostic Intravascular Catheter (K943739) as the inner lumen and an extruded outer lumen designed by Vascular Solutions. The inner lumen and hub assembly are purchased from Merit Medical in a non-sterile state. The pigtail catheter and outer lumen are joined together using an adapter junction placed near the proximal end of the pigtail catheter. The adapter junction incorporates a side port fitted with a stopcock/tube assembly for fluid flow and pressure measurement within the outer tube. The distal end of the outer tube is perforated with side holes to allow pressure measurement simultaneously with the sideholes at the tip of the pigtail. The dual lumen pigtail catheter is deployed through standard 8Fr guide catheters and will accommodate standard 0.038" diameter guidewires.

Intended Use:

The Vascular Solutions Langston™ Dual Lumen Pigtail Catheter is indicated for delivery of contrast medium in angiographic studies and for simultaneous pressure measurement from two sites. This type of pressure measurement is useful in determining transvalvular, intravascular and intraventricular pressure gradients.

Summary of Non-Clinical Testing:

Testing conducted included assessments of the design verification of the Dual Lumen Pigtail Catheter along with biocompatibility assessments. The results of this battery of tests confirmed the suitability of the Dual Lumen Pigtail Catheter for its intended use.

K041909
page 2 of 2

Summary of Clinical Testing:

No clinical evaluations of this product have been conducted.

Predicate Devices:

The Dual Lumen Pigtail catheter is similar in intended use and function to the Cordis Dual Lumen Pressure Monitoring Catheter (K914141), the USCI Cardiovascular Catheter (K943739), and the Merit Medical Softouch Diagnostic Intravascular Catheter (K810412).

Conclusions:

The Dual Lumen Pigtail Catheter is substantially equivalent to the Cordis Dual Lumen Pressure Monitoring Catheter, the USCI Cardiovascular Catheter and the Merit Medical Softouch Diagnostic Intravascular Catheter. The testing performed confirms that the Dual Lumen Pigtail Catheter will perform as intended.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 23 2004

Vascular Solutions, Inc.
c/o Ms. Sara L. Coon
Sr. Regulatory Affairs Associate
6464 Sycamore Court
Minneapolis MN 55369

Re: K041909

Trade Name: Vascular Solutions Langston Dual Lumen Pigtail Catheter (DLP)
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: II (two)
Product Code: DQO
Dated: July 13, 2004
Received: July 15, 2004

Dear Ms. Coon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

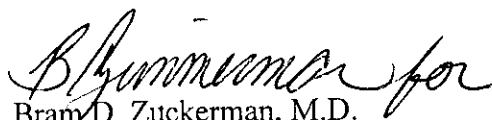
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Page 2 –Ms. Sara L. Coon

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4648. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in cursive script, appearing to read "B. Zuckerman for".

Brad D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K 041909

Device Name: Vascular Solutions Langston™ Dual Lumen Pigtail Catheter

Indications for Use:

The Vascular Solutions Langston™ Dual Lumen Pigtail Catheter is indicated for delivery of contrast medium in angiographic studies and for simultaneous pressure measurement from two sites. This type of pressure measurement is useful in determining transvalvular, intravascular and intraventricular pressure gradients.


Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K041909

Page 1 of 1